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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,437	06/25/2001	Yoko Aida	P20825	3769

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EXAMINER	
STUCKER, JEFFREY J	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,437	AIDA ET AL.	
	Examiner	Art Unit	
	Jeffrey Stucker	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,12-15 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,4,6 and 15* is/are allowed.

6)☒ Claim(s) *5,7,12,13 and 20-22* is/are rejected.

7)☒ Claim(s) *14 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office Action is in response to the amendment filed 12/1/05. Claims 1, 3-7, 12-15, and 20-22 are pending. Claims 1, 3, 4, 6, 14, and 15 are not rejected and claims 5, 7, 12, 13, and 20-22 are under final rejection.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is withdrawn in view of the cancellation of this claim.

The rejection of claims 1 and 5 as vague and indefinite because of the unclear language "an isolated protein as being Vpr protein" is withdrawn in view of the amendment of these claims.

The rejection of claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of this claim.

The objection to claims 3-4, 6, 14, and 15 as being dependant upon rejected claims is withdrawn.

Claims 1, 3, 4, 6, 14, and 15 are now directed to allowable products by virtue of the amendment filed 12/1/05. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 5, 7, 12, 13, and 20-22, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 5, 7, 12, 13, and 20-22 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office Action mailed on 8/24/04 is hereby withdrawn.

Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 4.

Claim 20 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 12.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after

allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following are new rejections necessitated by Applicant's amendment:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 is considered to be new matter. The Examiner has carefully reviewed the portions of the specification as indicated by Applicant in the second paragraph of response and failed to find any support for a "pharmaceutical composition".

The most closely related teaching in the specification is directed to a "medicament".

Claims 5, 7, 12, 13, and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)

the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The nature of the invention is directed to a pharmaceutical composition comprising HIV Vpr truncated 15 amino acids from the C terminal; methods of using HIV Vpr truncated 15 amino acids from the C terminal for treating or preventing AIDS; and methods of using a gene encoding HIV Vpr truncated 15 amino acids from the C terminal for treating or preventing AIDS. The breadth of the claims is broad. The claimed compositions (HIV Vpr truncated 15 amino acids from the C terminal and the gene encoding it) are claimed by name without claiming or describing the specific sequence of the claimed invention.

The quantity of experimentation necessary is high and the relative skill of those in the art is high. The state of the prior art in regards to the sequence and structure of HIV Vpr and the nucleic acid encoding it is relatively high. However, the art is not developed in a pharmaceutical composition

comprising HIV Vpr or a gene encoding it to treat or prevent AIDS.

The predictability or unpredictability of the art, and unpredictability demonstrated by the years of effort and nothing to show for it in regards to a pharmaceutical compositions and methods of treating or preventing AIDS. The claimed protein, and the gene that encodes it, "Vpr truncated 15 amino acids from the C terminal" is apparently novel and unknown for treating or preventing AIDS.

The amount of direction or guidance presented is very limited. The presence or absence of working examples in the specification is limited to only one working example of transforming a HeLa cell line with a nucleic acid sequence encoding a truncated HIV Vpr protein. The protein is known, and expected, to be toxic (as required by the claims: "apoptosis inducing agent") and, as expected, the cells expressing the toxic protein showed induction of apoptosis. In addition, HeLa cells are not representative of HIV infection and do not correlate with infection. HIV infects CD4 lymphocytes which HeLa cells are not; HeLa cells are lab adapted cervical cancer cells and are not found *in vivo* nor are relevant as a model of HIV prevention or treatment. Other relevant considerations are the existence of latent forms of the virus, the ability of the virus

to evade immune responses in the central nervous system due to the blood-brain barrier, and the complexity and variation of the elaboration of the disease. The existence of these obstacles establish that the contemporary knowledge in the art would not allow one skilled in the art to make and use the claimed invention with a reasonable expectation of success and without undue experimentation.

In addition, Vpr is toxic and can induce apoptosis in non-HIV infected cells. Infected cells produce Vpr by virtue of the infection. An apoptosis inducing pharmaceutical composition comprising truncated Vpr would reinforce the action of HIV vis-à-vis cell destruction, even of uninfected cells. Applicant has not taught how one can apply the "pharmaceutical composition" so as to treat or prevent AIDS without wholesale apoptosis in healthy cells.

The instant invention, based on the evidence as a whole, in light of the factors articulated by the court in *In re Wands*, lacks an enabling disclosure.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.

JEFFREY STUCKER
PRIMARY EXAMINER